U.S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 90-03

EA No. 90-222

Docket No. 030-08456

Licensee: Veterans Administration Medical Center
3350 La Jolla Village Drive
San Diego, California 92161

Inspection at: Same as above

Inspectors: James L. Montgomery — 1/3/91
James L. Montgomery, Senior Materials Specialist — Date Signed

J. Frank Pang — 1/3/91
J. Frank Pang, Radiation Specialist — Date Signed

James L. Montgomery for — 1/3/91
Scott Moore, Health Physicist — Date Signed

James L. Montgomery for — 1/3/91
Vivian Campbell, Materials License Reviewer — Date Signed

Approved by: James L. Montgomery for — 1/3/91
Robert J. Pate, Chief, Nuclear Materials and Fuel Fabrication Branch — Date Signed

Inspection Summary:

Inspection on November 2-4, 1990 and December 10-14, 1990 (Report No. 030-08456/90-03)

Areas Inspected: This was a special announced reactive team inspection conducted in response to a radioactive contamination incident, medical diagnostic misadministration, and occupational overexposure which occurred at the Veterans Administration Medical Center, San Diego, (VAMC/SD) between November 1, 1990 and November 26, 1990. The inspection included an examination of the licensee's organization and management controls; radiation safety training program; internal audit program; radiation surveys; internal incident investigations; Radiation Safety Committee actions; laboratory radiation safety; radioisotope handling; Confirmatory Action Letter response; dose calibrator quality assurance; Molybdenum 99 breakthrough testing; and independent measurements.

Results: Eleven apparent violations and no deviations were identified during the inspection. The apparent violations are summarized as follows:

A. Principle Investigators not assuming responsibility for radiation safety assigned to them by licensee management. (Section 7)

B. Inadequate radiation safety training. (Section 8, repeat violation)

C. Missing and inadequate radiation surveys. (Section 10)

D. Recording of incorrect radiation survey units. (Section 10, repeat violation)

E. Failure to use a syringe shield while administering licensed material to a patient. (Section 11)

F. Radiation overexposure exceeding 10 CFR Part 20 limits for the hand. (Section 11)

G. Failure to use an extremity dosimetry device. (Section 11)

H. Unauthorized person allowed in a restricted area. (Section 11, repeat violation)

I. Inadequate dose calibrator constancy check. (Section 12)

J. Inadequate dose calibrator linearity test. (Section 12)

K. Inadequate Molybdenum 99 breakthrough testing. (Section 12)

DETAILS

1. Persons Contacted

Licensee

*Thomas Trujillo, Medical Center Director
*Jacqueline Parthemore, M.D., Chief of Staff
*Robert Stevens, Administrative Assistant to the Director
Robert Engler, M.D., Associate Chief of Staff, Research Service
Samuel Halpern, M.D., Chief, Nuclear Medicine Service
Stephen Baird, M.D., Chief, Laboratory Service
*Gilbert Greenspan, M.D., Nuclear Medicine Service
David Yeung, M.D., Nuclear Medicine Service
Phillip Hagan, M.S., Radiopharmacist, Nuclear Medicine Service
*John Verba, Ph.D., Radiation Safety Officer
Dave Anderson, Technical Assistant, Nuclear Medicine Service
*Jim Matthews, Radiation Safety Technician
Helen Ranney, M.D., Distinguished Physician, Dept. of Medicine
William Wachsman, M.D., Ph.D., Acting Chief, Hematology/Oncology
Hailan Zhang, M.D., Researcher, Hematology/Oncology
Wolfgang Klump, Ph.D., Post-Doctoral Researcher, Hematology/Oncology
Lory Walls, Senior Research Assistant, Hematology/Oncology
Robert Parks, Watch Coordinator, Police and Security Service
Kimberly Goodman, Laboratory Assistant, Hematology/Oncology
Russell Cain, Chief Nuclear Medicine Technologist
Ron Burkes, Chief Administrative Technologist
Emmett Mayhorne, Chief of Personnel Service
Karl Hostetler, M.D., Metabolism Principle Investigator
Mike Gardner, Metabolism Senior Technician
Kristine Wright, Metabolism Technician
Lynn Deftos, M.D., Endocrinology Principle Investigator
Daryl Westerback, M.D., Endocrinology Staff Research Associate II
David Brandt, Ph.D., Endocrinology Post Doctoral Researcher
Douglas Richman, M.D., Infectious Disease Principal Investigator
Sara Albanil, Infectious Disease Staff Research Associate
Pascal Meylan, Ph.D., Infectious Disease Post Doctoral Researcher

Non-Licensee

Ken Helm, Radiation Safety Officer, UCSD
Frank Bold, Senior Health Physicist, San Diego County Department of Health Services

*Attended exit meeting on December 14, 1990.

2. Background and Purpose of Inspection

This was a special reactive team inspection conducted in response to radiation incidents reported to the NRC by the licensee's Radiation Safety Officer (RSO) on November 2 and November 26, 1990. A previous incident involving the unauthorized transfer of licensed material had been reported to the NRC by the RSO on August 20, 1990. A special reactive inspection was conducted in response to the previous incident and is documented in inspection report 90-02 which was sent to the licensee as an enclosure to a letter dated November 6, 1990.

3. Description of Radiation Incidents

A. Phosphorous-32 Contamination Incident

On or about November 1, 1990 a small amount of radioactive phosphorous-32 (P-32) tagged compound used in molecular biology research was spilled or dripped onto the floor of a Hematology/Oncology Research Laboratory (H/O) on the sixth floor of the VAMC/SD. The contamination was first discovered by two laboratory researchers when radiation surveys were conducted during the late evening hours of November 1st.

Upon further survey, contamination was detected on the floor in the hallway outside of the laboratory, on laboratory bench tops and other surfaces. The researchers attempted to clean up the radioactivity throughout the night and into the early morning hours of November 2nd. Radiation warning tape was placed around the contaminated lab areas. Contamination of several thousand disintegrations per minute (DPM) was detected on at least one of the researcher's shoes. By 6:00 AM, November 2nd, both researchers had left the laboratory and returned to their private residences without reporting the incident to anyone. Their final surveys indicated the hallway outside the contaminated laboratory was successfully decontaminated.

At approximately 7:45 AM, November 2nd, a Laboratory Technician reported for work and noted the contaminated laboratory and radiation warning tape. The Technician immediately left the H/O laboratories and walked to the elevator, descended to the third floor and entered the office of the H/O Principle Investigator (PI) to report the contamination. The H/O PI and the Technician immediately returned to the contaminated laboratory. Radiation surveys conducted at this time indicated contamination on the Technician's shoes. At approximately 8:15 AM the H/O PI reported the incident to the Radiation Safety Office. The Radiation Safety Officer and Radiation Safety Technician began to survey numerous areas of the VAMC and detected widespread contamination, later confirmed to be P-32, ranging from several hundred to several thousand DPM. Survey and decontamination efforts eventually involved dozens of people and extended into the late evening hours of November 2nd. Contaminated areas detected within the VAMC included laboratories, hallways, elevators and entry ways. Contamination was also measured on employees' personal effects such

as shoes and clothing and in living quarters. Eventually all contaminated areas, equipment and personal items were either decontaminated or held in storage for decay to background by the licensee or health physics personnel from the University of California at San Diego (UCSD). UCSD assistance was requested by the VAMC/SD to provide additional trained personnel to assist with the extensive radiation surveys that had to be performed to determine the extent of the contamination spread.

At 2:15 PM, November 2nd, the licensee reported the incident to the NRC Region V office. At 11:30 PM on November 2nd, an inspection team from the NRC Region V office arrived at the VAMC/SD to perform independent radiation surveys and investigate the incident and its cause. The four member NRC team, consisting of two Radiation Specialists, a Branch Chief and a Public Affairs Officer, confirmed the licensee identified contamination and located several previously unknown small areas of low level contamination. Entry into potentially contaminated areas by the NRC Radiation Specialists were made only after surveying each floor area prior to stepping in the area surveyed. Based on these surveys, no NRC personnel made contact with any contaminated areas. On several occasions during surveys conducted on November 2-4, the NRC team monitored the bottom of their shoes and no contamination above natural background was detected. On November 3rd, during a survey of a vacuum cleaner used to decontaminate floor areas, some vacuum cleaner dust contaminated the bottoms of shoes belonging to two NRC personnel. The contamination was immediately detected and the shoes removed and placed in sealed plastic bags by the VAMC/SD RSO for later decontamination. Shoe covers supplied by the licensee were then used by the NRC personnel and no further contamination occurred. The NRC team inspection and surveys continued on November 3rd and 4th.

On November 6, 1990, NRC Region V issued a Confirmatory Action Letter to the licensee. The letter confirmed an agreement reached between the licensee and NRC Region V management during a telephone conference that (1) an investigation would be initiated by the licensee to determine the cause(s) of the contamination and the adequacy of contamination control programs; (2) use of licensed material in the H/O Research Laboratories on the sixth floor West, D Pod would cease until the circumstances of the contamination were known and corrective action was taken to prevent recurrence; and (3) the findings were reviewed with the NRC prior to November 30, 1990.

B. Medical Diagnostic Misadministration Incident

On November 26, 1990 the licensee reported a diagnostic misadministration to NRC Region V in accordance with 10 CFR 35.33. The misadministration occurred when a patient was inadvertently administered 168 millicuries of technetium-99m pertechnetate instead of the intended 5 millicuries of indium 111 tagged monoclonal antibody.

Early in the morning of November 26th the licensee's radiopharmacist calibrated 237 millicuries of technetium-99m pertechnetate which he had placed in a syringe to be used in his quarterly dose calibrator linearity test. Also during about the same time, at the request of a Nuclear Medicine Physician, the pharmacist began to prepare a 5 millicurie dose of indium-111 labeled antibody for administration to a patient participating in an Investigational New Drug (IND) research protocol. At approximately 10:15 AM the physician instructed his Technical Assistant to obtain the indium-111 from the Nuclear Medicine Preparation Lab. The Technical Assistant erroneously picked up the syringe containing technetium-99m pertechnetate which had been prepared for the dose calibrator. Statements made by licensee personnel who handled the syringe were nebulous regarding the type and content of an identifying label on the syringe. The Technical Assistant stated he did not understand the notations contained on labels used in nuclear medicine procedures. The Physician stated he thought the label said "Indium-111, MOAB". Licensee personnel, including the RSO, who first viewed the label on the empty syringe following the dose administration stated it read technetium-99m. The Technical Assistant and physician were wearing gloves and body film badges but were not wearing ring or wrist badges.

Shortly after 10:15 AM, the physician received the syringe from the Technical Assistant and preceded to attempt to connect it to a "butterfly" apparatus used in the injection process with an infusion device. Several attempts to make the proper connections and use a three-way stopcock valve were unsuccessful. The Physician decided to abandon the attempts to connect these devices and instead proceeded to inject the contents of the syringe into the patient using a standard needle. No syringe shield was used by the Physician when handling the syringe. The RSO has estimated the total time in which the unshielded syringe was held by the Physician to be from 20-25 minutes. The licensee has calculated a total dose to the Physician's right hand to be 40 rem and has reported this dose as an overexposure in accordance with 10 CFR 20.405.

During the infusion the Technical Assistant was disposing of some of the contaminated items used in the earlier infusion attempts. During the disposal process the Technical Assistant removed his left glove to unlock a door. He then returned to the patient where the Physician was completing the infusion. During the final clean up of the infusion area, the Physician noticed a drop of contamination on the injection table which he proceeded to clean up in the presence of the Technical Assistant. Somewhere between removing his glove to unlock the door and the contamination clean up, the Technical Assistant contaminated the skin of his left hand with technetium-99m.

Shortly after the infusion of the wrong radioisotope (misadministration) was completed, the Technical Assistant asked the Physician when he wanted to administer the Indium 111 dose. The Physician replied that he had already finished and at this point the misadministration was discovered.

Within thirty minutes of the completion of the misadministration an endocrinologist at the VAMC/SD was consulted concerning dose reduction methods to be employed with the patient. The patient was given ten drops of Lugols solution to block further iodine uptake and one gram of sodium perchlorate to flush the thyroid gland and speed the elimination of technetium-99m. These treatments were considered successful. The patient remained in the medical center overnight. The following morning, November 27th, a whole body scan was conducted and indicated most of the technetium-99m was in the large and small intestine.

C. Unauthorized Use and Transfer of Licensed Material Incident

On March 9, 1989 unauthorized use and transfer of licensed material occurred at the VAMC/SD. Following a report of the incident and subsequent investigation of the circumstances by the licensee, an inspection was conducted by an NRC Region V inspector and an investigator from the Region V Office of Investigations. The inspection findings are described in Inspection Report 90-02, dated November 6, 1990. Four violations were identified but not cited in accordance with the enforcement discretion criteria in paragraph V.G. of 10 CFR Part 2, Appendix C, "General Statement of Policy and Procedure for NRC Enforcement Actions". All four were initially identified by the licensee and were either a Severity Level IV or V violation. This incident is mentioned here because it is considered to serve as another example of management ineffectiveness described in Section 7 of this report.

4. Licensee Internal Investigating Committees

In response to the P-32 contamination incident the VAMC/SD Director appointed a three person committee to determine the cause of the contamination, its spread outside of the laboratory, the amount of radioactive material spilled, and whether the incident was the result of an intentional act or negligence. The Director also requested that an evaluation be made as to how the VAMC/SD should respond to such an incident and to offer suggestions which would improve the radiation safety program.

The committee completed its investigation and written report on November 5, 1990 and the VAMC/SD Director submitted the report to NRC Region V by letter dated November 27, 1990. After extensive interviews and reenactments of the possible scenarios which could explain the spill and contamination spread, the committee concluded that the spill probably occurred in one or more of the following ways:

- P-32 contaminated electrophoresis gel dripped on to the floor during transport of gel plates from one bench top to another.

- A small amount of P-32 spilled from a vial cap or pipette tip on to the floor.

- A nonradioactive resin known as "Sephadex" combined with spilled P-32. Then upon drying into a fine powder, the

contaminated "Sephadex" was transported to various areas of the lab by air currents largely created by a ventilation system producing an abnormally high air velocity.

The committee report stated that based on laboratory records and radioactivity measurements, the contaminant was P-32 and that approximately 40 microcuries or less had been spilled and tracked around. The committee found no evidence that the incident was intentional or the result of negligence. Several violations of the VAMC/SD Radiation Safety Procedures were noted by the committee who also offered numerous recommendations for improving the radiation safety program. A root cause for contamination events was not determined and in fact, the committee concluded that the incident was "...the outcome of events each one of which was itself unlikely" and ..."culpability for the incident, if present, was questionable."

The NRC inspection findings did not reveal any new information concerning the cause of the spill and contamination spread. The actual cause will probably never be known. However, one of the root causes of not only this incident, but other problems and violations described in this report, was determined to be inadequate radiation safety training by the PI and is described in the Organization and Management Controls, and Training sections of this report.

On November 29th, a second three person committee was appointed by the VAMC/SD Chief of Staff and Director to investigate the misadministration incident. This committee was formally known as a Quality Assurance Board of Investigation and was formed in accordance with the provisions of 38 CFR 17.50(c)(2) since the incident involved patient medical care. The committee completed an investigation and submitted their undated written report to the VAMC/SD Director prior to the due date of December 15th. The committee's findings and recommendations were similar to what is described in this report. The actual contents of the committee report are considered confidential by the licensee and references the "U.S.C. & 3305."

5. Radiation Safety Committee Actions

As of December 14, 1990, no Radiation Safety Committee meetings had been held to discuss the misadministration incident. On November 9, 1990 the RSC held a special meeting to receive a briefing from the RSO on the status of the contamination clean-up, radiation surveys and NRC inspection team activities. The meeting minutes did not indicate the RSC made any recommendations for corrective actions.

On November 28, 1990 another special RSC meeting was held to provide an update on the P-32 contamination and to decide what RSC action was necessary. The RSC and RSO discussed the reopening of the PI's H/O laboratory with NRC concurrence. The H/O PI attended the meeting at the RSC's invitation and discussed the violations of VAMC/SD radiation safety procedures which he had identified in his laboratory. He attributed several of the violations to inadequate training of one researcher believed to be responsible for the spill. He assumed the researcher, who he had recently hired, was well trained in radiation

safety procedures because of previous experience at a large university. The PI also described six laboratory improvements which he planned to implement. These improvements were later discussed with the NRC Region V staff during a telephone conference call.

The RSC expressed concern about the researcher's competence to use radioactive materials. The H/O PI assured the RSC that the researcher was very conscientious and competent. The RSC voted unanimously to allow the H/O PI to reopen his laboratory for radioactive material use after the RSO verified corrective actions and the investigative report had been reviewed with the NRC Region V staff.

The RSC also discussed a new policy made by the VAMC Director to allow the RSC to close a laboratory in non-compliance for three months. It was decided to continue discussion of this item at the next RSC meeting scheduled in January 1991. The RSO concluded the meeting by noting an increased awareness by the PIs to actively participate in the overall radiation safety programs in their respective laboratories which "...is a part of the foundation of the NRC program."

As evidenced by the two special meetings described above, the RSC appears to be actively involved in the contamination incident followup and corrective actions. However, no root cause analysis for the incident was performed or discussed and the minutes reflect the erroneous belief that PI involvement in the radiation safety program is an NRC initiative. Nothing in the minutes referred to discussions regarding the PI responsibilties being VAMC/SD policy.

No apparent violations or deviations were identified.

6. Compliance With Confirmatory Action Letter

On December 3, 1990 the licensee held a conference telephone call with NRC Region V personnel to discuss compliance with the three conditions of the NRC Confirmatory Action Letter (CAL) dated November 6, 1990. The licensee presented information concerning their incident investigation including a review of the adequacy of the VAMC/SD contamination control program. The licensee concluded that the program was deficient and discussed a revised procedure which had been issued on November 28, 1990.

The circumstances surrounding the spill and contamination spread were discussed and the licensee presented several possible explanations for the incident. Corrective actions to prevent recurrence were also discussed and included seven actions taken or planned by the H/O PI.

Following the conference call, the licensee faxed information to the NRC Region V inspectors documenting the above actions. The NRC Region V staff concluded that the licensee had adequately met the provisions of the CAL. The licensee was informed that the NRC staff had no objections to the reopening of the H/O PI's laboratories for radioactive material use under the VAMC/SD license and at the discretion of the RSO, RSC and VAMC/SD management.

No apparent violations or deviations were identified.

7. Organization and Management Controls

Licensee management has been extensively involved in the recent incidents including the unauthorized transfer of licensed material described in the NRC inspection report 90-02, dated November 9, 1990. The Medical Center Director, Assistant to the Director, Chief of Staff, RSC, and the RSO are actively involved in the radiation safety program. Nevertheless, the licensee continues to experience significant radiation incidents which directly involve PIs and physicians who administer large research programs and staff. The PIs also usually have extensive experience with using radioactive materials in their research. The cornerstone of the licensee's program for radiation safety is the stated policy and requirement that the PIs are responsible for the safe practices and radiation safety training of persons under their control. The PIs are assigned the responsibility to assure safety and compliance with radiation safety procedures at the VAMC/SD and the NRC regulations and license conditions. The licensee's August 1, 1989 Radiation Safety Manual is referenced in license condition 21 and repeatedly states the radiation safety responsibilities that the PIs have for their respective laboratories and employees.

Specifically, the H/O PI did not assure that his employees and others under his control were familiar with and followed radiation safety procedures described in the August 1, 1989 Radiation Safety Manual, and 10 CFR Parts 19 and 20. Failure to follow required procedures and regulations contributed to the P-32 contamination incident described in Section 3.A. above. On November 2nd extensive surveys and evaluations were made in an attempt to better define the extent and level of contamination associated with the H/O PI's staff, their personal effects and the VAMC/SD. Later in the day on November 2nd the H/O PI left the VAMC/SD and was not available for several days to lead the clean-up. He also reportedly declined the RSO's request to provide a H/O staff member to act in his behalf while the H/O PI was absent. The PI indicated that since the contamination was outside of his laboratory, the responsibility for evaluation and clean-up rested with VAMC management and the RSO.

In another incident, described in Section 3.B. above, a PI who was also a physician, misadministered a diagnostic radiopharmaceutical. An employee under the physician's supervision contributed to the misadministration due primarily to the physician's failure to assure safety and compliance by his staff with the licensee's Radiation Safety Manual, and 10 CFR Parts 19, 20 and 35.

One apparent violation was identified.

8. Radiation Safety Training Program

The licensee's radiation safety training program consists of two major areas. First, a basic radiation safety training course is given by the RSO or the RSO's Radiation Safety Technician. This course covers the requirements in the licensee's Radiation Safety Manual, dated August 1, 1989, and basic laboratory and health physics procedures. The second area of training is the responsibility of each PI who uses radioactive material. The licensee's Radiation Safety Manual specifies the PI

training responsibilities which include instruction of personnel in wearing monitoring devices and surveying of hands and clothing. The licensee's ALARA program, contained in the Radiation Safety Manual, requires authorized users to ensure that persons using radioactive material under their supervision are trained and educated in good health physics practices and in maintaining radiation exposures as low as reasonably achievable.

10 CFR 19.12, entitled "Instructions to Workers", requires individuals working in restricted areas to be instructed in precautions or procedures to minimize exposure, using protective devices, and prompt reporting to the licensee of conditions which may lead to or cause an NRC violation or unnecessary exposure to radiation.

A researcher in the H/O laboratory was not adequately trained by the H/O PI or anyone else. The H/O PI reported to the RSC on November 28, 1990 that he assumed the researcher was capable of handling radioactive material safely since he had used radioisotopes for several years at another institution. The November 28, 1990 RSC meeting minutes summarized discussions between the RSC and the H/O PI about the H/O laboratory researcher's training as follows: "...no lab coat, no film badge, using centrifuge in tissue culture lab, not monitoring during experiment, not properly decaying or using the proper assay date was an outcome of his not being properly trained". This lack of training and familiarization with VAMC/SD facilities and equipment was a major contributing factor to the P-32 spill and resultant contamination spread.

A Technical Assistant working under the supervision of a Nuclear Medicine Physician was not adequately trained in radioisotope handling procedures and nuclear medicine syringe labeling. Failure to provide adequate training and supervision resulted in the Technical Assistant selecting the wrong syringe containing licensed material and later contaminating his ungloved hand with the same material. The training of the physician was also inadequate and contributed to his failure to use a syringe shield and wear a ring or wrist dosimetry device. The handling of the unshielded syringe resulted in a radiation overexposure to the physician's hand.

The inadequate training of the H/O researcher was identified by the NRC Region V inspection team on November 3, 1990 and was identified as a violation by the H/O PI during the November 28, 1990 meeting with the RSC. The training violation for the Technical Assistant and Nuclear Medicine Physician was identified by the NRC inspection team on December 14, 1990. The violation is also repetitive (see NRC inspection report 90-02 dated November 6, 1990).

One apparent repeat violation was identified.

9. Internal Audits

The RSO and his Radiation Safety Technician usually visit radioisotope research laboratories on at least a weekly interval. These visits are usually for the purpose of delivering a radioisotope shipment or handling

other administrative details. Occasionally these weekly visits involve discussions of radiation safety matters and the PI and his staff are given the opportunity to ask questions. However, formal detailed audits are not normally conducted except during the annual program review and training conducted by the RSO with each PI.

Frequent, thorough and effective audits have not been conducted due to resource limitations in the radiation safety program. Also, the frequency of radiation surveys in the laboratories and general areas have been significantly reduced over the past two years. Meaningful and frequent audits are essential to provide the necessary quality assurance which management needs to confirm that the radiation safety program is achieving the level of compliance intended. Strict disciplinary action for violators is not by itself an effective deterrent. A good audit/quality assurance program must be implemented either by the Radiation Safety Office or other VAMC/SD organizational group to assure management that the overall radiation safety program is effective.

In particular the NRC inspectors noted that no one at VAMC/SD was performing reviews or audits of basic radioisotope handling procedures in laboratories. The PI's tended to assume that their personnel already had learned these techniques from previous work at other institutions. Failure to either understand or follow these basic handling procedures lead to the P-32 spill and contamination spread, the misadministration, hand overexposure, and skin contamination. For example, during a reenactment with the NRC inspectors of the H/O researcher's P-32 handling techniques, several steps were identified where contamination/spills could occur. These steps included pipette use, gel-plate handling, centrifuge use and use of reagent chemicals such as "Sephadex". If the researcher does not take sufficient precautions on each of these steps, a spill could occur. In the Nuclear Medicine Department the physician failed to follow several basic radioisotope handling procedures.

The inspectors reviewed the records for the periodic wipe test performed by the Radiation Safety Technician. From the review the inspectors concluded that over the past few years (1988-1990) the number of wipe tests performed have been greatly reduced. In the 1987-1988 time period the periodic wipe tests were performed either weekly or monthly. These wipe tests were done in 1989 and 1990 approximately once or twice a year. The areas on the sixth floor were tested by the Radiation Safety Technician in February 1989 and March 1990. The Radiation Safety Technician stated that each lab is also wipe tested weekly by the lab staff, but discussions with the RSO indicated this weekly data is not routinely reviewed by the Radiation Safety Office nor are they trended. The inspector's noted that the independent measurements by the VAMC/SD Radiation Safety Office was less frequent than the independent tests conducted at similar facilities.

The licensee's Radiation Safety Manual does not contain specific audit requirements other than the annual review process described above. Therefore, no apparent violations related to this area were identified. Nevertheless, for reasons described above, the NRC inspectors consider internal audit improvements to be vital to achieving an effective radiation safety program.

While the internal audit system needs improvement, the licensee implemented an external independent audit to provide insight into needed improvements. During the week of December 3, 1990, two RSOs from other VAMC facilities conducted an extensive radiation safety audit and reported their findings to VAMC/SD management. The audit results indicated the need for improvement in overall laboratory radiation safety procedures, training and audit functions.

No apparent violations or deviations were identified.

10. Radiation Surveys

The licensee identified several violations of their Radiation Safety Procedures Manual related to radiation surveys. Failure to specify wipe test action levels, inadequate wipe analysis and documentation, failure to monitor P-32 experiments, and failure to conduct wipe surveys when required were identified by the RSO as violations during the November 28, 1990 RSC meeting.

On December 3, 1990 a PI working with approximately one millicurie of tritium detected contamination in two of his laboratories. In a memorandum to the RSO dated November 29, 1990 the PI identified four radiation survey violations of the licensee's radiation safety procedures. The violations involved inadequate recording of wipe test results, failure to rewipe some decontaminated areas and missing wipe test data. Although not required, the RSO reported the contamination to NRC Region V. The PI and his staff adequately decontaminated the laboratories with no further spread of the tritium.

The NRC inspectors reviewed the H/O radiation survey procedures and records and noted the following additional examples of failure to conduct adequate surveys and use of incorrect radiation survey units in accordance with 10 CFR 20.201(b) and 10 CFR 20.401(b) respectively:

- H/O laboratory survey records for June, 20 and 28; July 30, and August 6, and 22, 1990, indicated that recounts of cleaned-up contaminated areas were performed on the next day or later.

- H/O laboratory survey records for May 4, 14, and 25; and June 1, 1990, did not show a recount of previously contaminated areas.

- Records of analysis of surveys conducted in the H/O laboratory on May 18, June, 20, and 28, and September 26, 1990, showed that areas thought to have been decontaminated in fact remained contaminated without any further surveys or followup.

- H/O laboratory contaminated areas identified by surveys on May 18; June 28; 30, and September 26, 1990, showed higher levels of radioactivity after recounting.

- Survey data was missing for the weeks of May 7 and June 4, 1990 in the H/O laboratory.

- H/O laboratory survey data for April 17, 24, May 4 and 18, and June 13 and 28, 1990, were incorrectly reported in units of counts per minute (CPM) instead of the required disintegrations per minute [10 CFR 20.401(b)]. This was cited as a violation during a previous NRC inspection.

Two apparent violations (one repeat) were identified.

11. Laboratory Radiation Safety and Radioisotope Handling

The contribution of poor radioisotope handling techniques to spills and contamination spread was previously discussed in Section 9 of this report. The licensee also identified several violations of their procedures in the H/O laboratories involving failure to wear a lab coat and film badge during radioactive material use; failure to record radioisotope use and account for radioisotope decay in records; and permitting an unauthorized visitor into a restricted area (repeat violation).

Other improper techniques and procedure violations were found to be the chief cause of the diagnostic misadministration, contamination and hand overexposure in the Nuclear Medicine Department.

Failure to read radioisotope labels on a vial and syringe led to administering the wrong radiopharmaceutical and wrong dose to a patient. Failure of a physician to use a syringe shield in accordance with 10 CFR 35.60(c) resulted in a licensee calculated overexposure of 40 rem to the physician's hand. This overexposure was reported to the NRC in accordance with 10 CFR 20.405. No dosimeter data is available for the hand exposure because the physician was not wearing a wrist or ring dosimetry badge as required by 10 CFR 20.202(a)(1).

In summary, allowing an unauthorized visitor in a restricted area, failure to use a syringe shield, failure to use extremity personnel monitoring dosimeter, and allowing an occupational worker to exceed the 10 CFR Part 20 quarterly extremity radiation exposure limit were identified as apparent violations.

Four apparent violations (one repeat) were identified.

12. Dose Calibrator Quality Assurance and Molybdenum Breakthrough Testing

Analysis of the licensee's dose calibrator quality assurance (QA) records and procedures demonstrated that the licensee's Radiation Safety Office audits had been ineffective in identifying deviations of requirements specified in 10 CFR Part 35. QA procedures routinely performed by the Radiopharmacist consisted of the daily accuracy/constancy test, linearity test, geometry test, and molybdenum breakthrough test. The Radiopharmacist performed a daily accuracy test by using calibration standards of Co-57, Ba-133, and Cs-137. The activity of each of these standards was measured at it's specific radioisotope setting, i.e., the Co-57 reference was measured at the Co-57 setting, etc. The Radiopharmacist indicated that he had used these three daily readings to measure the constancy of the dose calibrator. Commonly used radioisotope

settings, such as Tc-99m and I-131, had not been checked; therefore, the daily constancy requirement specified in 10 CFR 35.50(b)(1) was not satisfied. However, because of a misunderstanding based on a previous NRC inspection in 1985, the licensee was under the impression that this test was currently adequate to meet the constancy check requirement. Therefore, this is considered a non-cited violation.

Quarterly linearity tests reviewed during the inspection ranged from activities with a lower limit of 700 microcuries to an upper limit of 250 millicuries. 10 CFR 35.50(b)(3) requires, in part, that linearity testing must range in activities between the highest dose administered to a patient and 10 microcuries. The Radiopharmacist indicated that he had not been aware of the requirement to test linearity to the required lower limit of 10 microcuries. Notwithstanding the regulations as explained, he indicated that the Nuclear Medicine Department had not administered doses below 700 microcuries to patients.

10 CFR 35.204 requires, in part, that licensees not administer to humans a radiopharmaceutical containing more than 0.15 microcuries of Mo-99 per millicurie of Tc-99m. For each elution of the Mo-99/Tc-99m generator, the licensee must determine the concentration of Mo-99 by measuring the activity of Tc-99m expressed in millicuries and the activity or Mo-99 expressed in microcuries. Contrary to the above, the Radiopharmacist had not measured the total activity of the eluate, but instead had entered repetitive values which were estimates of the yield on specific days, i.e., 1600 millicuries on Monday, 1200 millicuries on Tuesday, 900 millicuries on Wednesday, etc. The Radiopharmacist stated that he had not assayed actual quantities of eluate because of his convictions to maintain his personal radiation exposure in accordance with the ALARA principle. Although the total activity of the Tc-99m eluate had not been determined, the Radiopharmacist indicated that he had attempted to measure the total activity of the Mo-99 contaminant. Review of the QA records maintained by the Radiopharmacist indicated repetitive entries of activities of <4 microcuries of Mo-99 per elution.

In summary, inadequate dose calibrator daily constancy checks, quarterly linearity tests and molybdenum 99 breakthrough tests were identified as apparent violations.

Three apparent violations were identified.

13. Independent Measurements

Beginning on November 2, 1990, the NRC inspectors conducted extensive radiation monitoring to independently confirm the licensee's surveys and to verify that no P-32 contamination remained. The inspection team identified contamination in the following areas:

Location	Contamination Level
Outside door from Lab area to Stairwell 10 Two spots on floor	450 dpm.; 600 dpm.
Hall outside door to room 6090 One spot on floor	600 dpm

Inside room 6090	
a) several spots on floor	200-400 dpm.
b) corner of rubber mat	1800 dpm.
Inside room 6095	
absorbent paper in	
a trash can	2000 dpm.
Elevator P-4	
Spot on floor	1200 dpm.
Elevator P-6	
Spot on floor	450 dpm.
Outside door from	
Lab area to Stairwell 2	
One spot on floor	200 dpm.

With the exceptions noted above (which are additional examples of failure to conduct an adequate survey) the NRC inspectors found no radiation levels above natural background.

On December 12, 1990 confirmatory measurements were conducted again in the H/O laboratories by the NRC inspector using a Ludlum Model 3 meter with a "pancake" probe (serial no. 022879). No radiation levels above natural background were detected. The licensee's survey meter located in the laboratory was a Victoreen Model 290 with a "pancake" probe. Using a Cesium 137 check source on the side of the licensee's meter it was determined that it read within 5% of the NRC instrument.

No apparent violations or deviations were identified.

14. Exit Briefing

On December 14, 1990 an exit briefing was held by the NRC inspection team with licensee management as indicated in section 1. The areas of PI responsibility for radiation safety and training were emphasized as the root causes for most violations. The licensee identified violations were summarized and the inspectors noted that the citations pertaining to an unauthorized laboratory visitor, inadequate training and incorrect radiation survey units, were repeat violations. The apparent violations and misadministration incident in the Nuclear Medicine Department were summarized last. The overexposure to the physician's hand was reviewed and it was noted that the NRC exposure calculations were in close agreement with the licensee's. The concluding remarks by the NRC Region V management representative emphasized the PI's responsibilities and the need for licensee management to effectively monitor and verify compliance before a significant incident occurs. The stern discipline policy for violators cannot by itself insure safe conditions. Management must effectively monitor the quality of radioisotope user compliance with safety requirements to preclude having to implement drastic disciplinary action which has always been taken after a serious incident has occurred. It was noted that the frequency of RSO audits and surveys was decreasing and that licensee management was considering various corrective actions including additional staff for the RSO office.